REMARKS

Introductory Comments:

Claims 18 and 21-23 were examined in the Office Action under reply and stand rejected under 35 U.S.C. §101; 35 U.S.C. § 112, first paragraph; and 35 U.S.C. §112, second paragraph. These rejections are respectfully traversed as discussed more fully below.

Overview of the Above Amendments:

Claims 21-23 have been cancelled and recitations therefrom added to claim 18. Thus, claim 18 now recites that the protein is an "unglycosylated, transmembrane protein." Additionally, claim 18 recites the molecular weight of the protein is "determined by SDS-PAGE" and the protein is "stable to acetone precipitation." Claim 18 has also been amended to delete the term "functionally equivalent variant" and recites the fragment "is a truncated form of the protein that lacks a functional portion of a transmembrane domain and binds the E2 protein of hepatitis C virus." Finally, this claim now recites that the method is for screening chemical compounds for ability to compete with HCV for binding to a host cell receptor.

New claims 24-32 have been added. Claims 24-27 pertain to the process by which the protein used in the method of claim 18 is made. New claim 28 relates to a method for screening for chemical compounds that mimic the HCV surface structure that binds to the HCV receptor. New claims 29-32 are analogous to claims 24-27.

Support for the foregoing amendments and new claims can be found in the original claims, as well as throughout the specification at, e.g., page 3, line 38 to page 4, line 1; page 4, lines 27-28; page 5, lines 9-11; page 5, lines 16-29; page 6, lines 15-17; page 8, lines 29-32; Example 3 and Example 5.

Cancellation of claims 21-23 and amendment of claim 18 is made without prejudice, without intent to abandon any originally claimed subject matter, and without intent to acquiesce in any rejection of record. Applicant expressly reserves the right to

file one or more continuing applications hereof containing the canceled or unamended claims.

Rejection Under 35 U.S.C. §101/112

Claims 18 and 21-23 were rejected under 35 U.S.C. §101 and §112, first paragraph, as lacking utility. The Office alleges "the claimed invention is not supported by either a credible asserted utility or a well-established utility." Office Action, page 2. The Office notes the previous claims read on "methods of identifying compounds capable of binding to the Hepatitis C virus (HCV) region responsible for binding to a host cell." Office Action, page 2. The Office argues the "methods described in the claims are identifying compounds that bind to a cellular protein, not a viral protein" and thus the methods appear "to be identifying compounds that could potentially compete with the HCV E2 proteins for binding to the cellular protein" as opposed to identifying compounds that bind to HCV.

Although applicant disagrees with the Office's assessment, claim 18 has been amended to recite a method for screening chemical compounds for ability to compete with HCV for binding to a host cell receptor, an embodiment that the Office acknowledges is useful. Thus, this basis for rejection has been overcome and withdrawal thereof is respectfully requested.

Rejection Under 35 U.S.C. §112, Second Paragraph:

Claims 18 and 21-23 were rejected under 35 U.S.C. §112, second paragraph as allegedly being incomplete for omitting a step "indicating how the ability to bind to the 24kd protein relates to the compounds ability to bind HCV." Office Action, page 4. As explained above, the current claims have eliminated the language objected to by the Office. Thus, this basis for rejection no longer applies and withdrawal thereof is respectfully requested.

Rejection under 35 U.S.C. §112, First Paragraph:

Claims 18 and 21-23 were rejected under 35 U.S.C. §112, first paragraph, as non-enabled. The Office recognizes the specification is "enabling for the claimed methods wherein the protein to which binding is being screened is the 24kd protein that binds to the HCV E2 protein." Office Action, page 4. However, the Office argues the specification "does not reasonably provide enablement for methods using any 'functionally equivalent' or fragment thereof." Office Action, page 4. In particular, the Office asserts:

> The claims are also not limited to the use of fragments or variants that have the ability of the 24kd protein to bind to the HCV E2 protein. Rather, they are drawn to methods of using any 'functionally equivalent' variant or fragment thereof...The application provides no guidance as to what variants or fragments may be considered functional equivalents of the indicated proteins as there is no description as to what features of the proteins are required for the HCV E2 binding function.

Office Action, pages 5-6. However, applicant respectfully submits the claims are indeed enabled throughout their scope.

It is well settled that the test of enablement is whether one reasonably skilled in the art could make or use the invention from the disclosures in the patent coupled with information known in the art without undue experimentation (*Ex parte Forman*, 230 USPQ 546 (P.T.O. Bd. Pat. App. & Int., 1986). In order to comply with the enablement requirement of 35 U.S.C. §112, first paragraph, the specification need only set forth such information as is sufficient to allow one of ordinary skill in the art to make and use the invention. How such a teaching is accomplished, either by the use of illustrative examples or by broad terminology, is of no importance since a specification which teaches how to make and use the invention in terms which correspond in scope to the claims must be taken as complying with the first paragraph of §112 unless there is reason to doubt the objective truth of the statements relied upon therein for enabling support (*In re Marzocchi*, 169 USPQ 367 (CCPA 1971)). The burden is on the Office to explain its reasons for the rejection and support the rejection with (i) acceptable evidence, or (ii) reasoning which contradicts the applicant's claim: the reasoning must be supported by current literature as a whole and the Office must prove the disclosure requires undue experimentation. *In re Marzocchi*, 169 USPQ 367, 369-70 (CCPA 1971). The Office has failed to carry its burden.

In fact, more than adequate information has been provided in order to enable one of skill in the art to make and use the invention. An extensive discussion of methods of making and using the 24 kD proteins and fragments thereof as claimed is found throughout the specification and examples. The described methods could readily be used to practice the invention without undue experimentation. The Office is reminded that even a large amount of experimentation is permitted under §112, first paragraph, provided it is routine. *Ex parte Jackson*, 217 USPQ 804, 807 (POBA 1982) (a claim is acceptable under §112 even if it requires extensive experimentation, as long as the experimentation is routine).

Nevertheless, the term "functionally equivalent variants" has been eliminated from the claims. Applicant submits the claimed fragments, i.e., those that lack a functional portion of a transmembrane domain, are enabled. One of skill in the art can easily

determine the presence of a transmembrane domain and how to enzymatically or chemically cleave the 24 kD protein in order to remove the domain. Fragments so obtained can be readily tested for binding to HCV E2 using the methods described in the specification. Thus, contrary to the Office's assertions, one of skill in the art could obtain functional fragments of the 24 kD protein, without undue experimentation. Withdrawal of the rejection under 35 U.S.C. §112, first paragraph is therefore respectfully requested.

CONCLUSION

Applicant respectfully submits that the claims define a patentable invention. Accordingly, a Notice of Allowance is believed in order and is respectfully requested.

Please direct all further written communications in this application to:

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Respectfully submitted,

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